

K091370
510(k) SUMMARY

8. 510(k) Summary

JUN - 5 2009

This 510(k) Summary is provided per the requirements of section 807.92(c).

510(k) Number: TBD
Owner Name: Bard Electrophysiology Division of C. R. Bard, Inc.
Address: 55 Technology Drive
Lowell, MA 01851
Contact Person: Julie Broderick
Director, Regulatory Affairs
Tel: 978-323-2220
Fax: 978-323-2222
Email address: julie.broderick@crbard.com
Alternate Contact: Ana Randall
Manager, Regulatory Affairs
Tel: 978-323-2348
Fax: 978-323-2222
Email address: ana.randall@crbard.com
Date Prepared: May 1, 2009

Device Trade Name: Radia™ Steerable Diagnostic Catheter
Device Common Name: Diagnostic electrode catheter
Class: Class II, 21 CFR 870.1220, Product Code DRF

Predicate Device(s):

- Orbiter ST Diagnostic Electrode Catheter (K992373)
- EP•XT Steerable Electrode Catheter (previously known as Bard Steerable Catheter) (K921872A)

Device Description:

The Radia™ Steerable Diagnostic Catheter is a steerable atrial mapping EP catheter with up to 20 electrodes. The device consists of a polymer shaft with platinum electrodes and internal steering wires mounted on a rotary-style handle for deflection of the catheter tip.

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Special 510(k) Submission for the
Bard Radia™ Steerable Diagnostic Catheter

Indication for Use:

Bard Electrophysiology's steerable diagnostic electrode catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

Comparison to Predicate Devices:

The Radia™ Steerable Diagnostic Catheter has the same intended use and fundamental scientific technology as the predicate devices. All technological characteristics of the Radia™ Steerable Diagnostic Catheter are substantially equivalent to the predicate devices including packaging, biocompatibility, sterilization, and labeling. Where minor technological and material differences exist between the proposed device and the predicate devices, performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the proposed device.

Summary of Non-Clinical Testing:

Bench testing of the Radia™ Steerable Diagnostic Catheter was performed to support substantial equivalence. Results of testing demonstrate that the Radia™ Steerable Diagnostic Catheter design meets product specifications and intended uses.

Statement of Equivalence:

The Radia™ Steerable Diagnostic Catheter has the same indications for use and technological characteristics as the predicate devices. Based on this and the design and engineering data provided in the pre-market notification, Radia™ Steerable Diagnostic Catheter has been shown to be substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2009

C.R. Bard, Inc.
Bard Electrophysiology
c/o Ms. Julie Broderick, RAC
Director, Regulatory Affairs
55 Technology Drive
Lowell, MA 01851

Re: K091370
Trade/Device Name: Radia™ Steerable Diagnostic Catheters
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II (Two)
Product Code: DRF
Dated: May 7, 2009
Received: May 8, 2009

Dear Ms. Broderick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

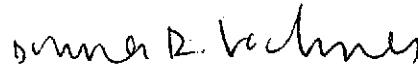
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7. Statement of Indications for Use

K091370

Indications for Use

510(k) Number (if known):

Device Name: Radia™ Steerable Diagnostic Catheter

Indications for Use:

Bard Electrophysiology's steerable diagnostic electrode catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

Contraindications:

The catheter should not be used in conditions where manipulation of the catheter would be unsafe (e.g., intracardiac mural thrombus).

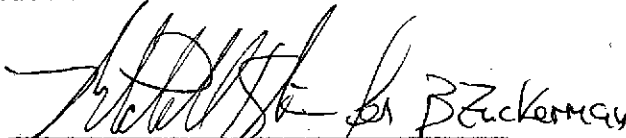
The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)



(Division Sign-Off) 6/5/09
Division of Cardiovascular Devices

510(k) Number K091370